REMARKS

In response to the Office Action of July 15, 2009, the present application has been carefully reviewed and amended. Entry of the present Amendment and reconsideration of the application are respectfully requested.

By this Amendment, Claims 14, 19, 20, 21, and 22 have been amended, and new Claims 28 and 29 have been added. Accordingly, Claims 14, 16-22, 28, and 29 are currently pending in this application, and no new matter has been added by these amendments and new claims.

In the current Office Action, Figures 17 and 18 were objected to, as was the amendment to the specification filed on February 3, 2009. Claims 19 and 20 were also rejected under 35 U.S.C. §112, second paragraph, as being indefinite, Claims 14, 17, and 19 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,089,103 to Smith ("Smith"), and Claims 14, and 16-19 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 3,726,269 to Webster, Jr. ("Webster"). In addition, Claims 16 and 18 were rejected under 35 U.S.C. §103(a) as being unpatentable over Smith in view of U.S. Patent No. 5,221,256 to Mahurkar ("Mahurkar"), and Claim 20 was rejected under 35 U.S.C. §103(a) as being unpatentable over Webster in view of U.S. Patent No. 6,231,498 to Pfeiffer et al. ("Pfeiffer").

Drawings

The drawings have been amended, and specifically, the blood flow arrows in Figures 17 and 18 (*see* Replacement Sheets 10/11 and 11/11) have been

amended to provide correspondence with the written description. Figures 17 and 18 now more clearly illustrate a thermodilution catheter placed with the blood flow. No new matter has been added by these amendments.

As the drawings are now believed to be in compliance with 37 C.F.R. §1.83(a), consideration and allowance of new Figures 17 and 18 is respectfully requested.

Specification

Applicant thanks the Examiner for proposing acceptable language for the text inserted after paragraph [0038] in the February 3, 2009 Amendment. Applicant has hereby amended this text in conformity with the Examiner's recommendations. Applicant has also amended paragraph [00142] to incorporate Figure 18. Consideration and allowance of these amendments to the specification is respectfully requested.

Claim Rejections under 35 U.S.C. §112

Claims 19 and 20 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Claim 19 depends from independent Claim 14, and both of these claims are currently amended. The amendments to claim 14 provide proper antecedent basis for the limitations of dependent Claim 19. Thus, Applicant believes that the objection to Claim 19 has been overcome. Reconsideration is respectfully requested.

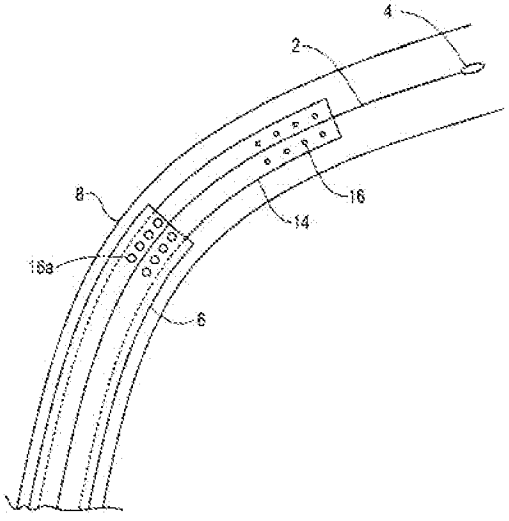
Claim 20 has also been amended to overcome the indefiniteness objection discussed above. Thus, reconsideration and allowance of Claim 20 is also respectfully requested.

Claim Rejections under 35 U.S.C. §102

Claims 14, 17, and 19 stand rejected under 35 U.S.C. §102(b), as being anticipated by Smith. Smith does not, however, disclose or suggest, among other things, calculating a blood flow rate as a function of passage of an indicator through a terminal port.

Instead, as shown in Figure 3 (reproduced below), Smith teaches a guide catheter 6, an optional auxiliary catheter 14, side holes 16a, 16 formed in the catheter 6 and in the auxiliary catheter 14, and a guide wire 2 having a sensor 4 disposed at its distal end.

FIG. 3



When a thermodilution measurement is to be performed using the Smith device, the guide catheter 6 is filled to the distal opening with cold saline, a

small bolus amount of the saline is then injected into the guide catheter 6 at the proximal end, thereby expelling a corresponding amount of saline from the distal opening of the guide catheter 6 and from the side holes 16a, 16 into a blood vessel 8. When the saline passes a temperature sensor on the distal tip of the guide catheter 6, the temperature sensor registers a temperature gradient and a timer is initiated. When the injected bolus passes the sensor 4 at the distal tip of the guide wire 2, another temperature gradient is recorded and the system then calculates a flow parameter.

There is, however, no disclosure of compensating for, or in any way distinguishing passage of the injected bolus through a terminal port in Smith's calculations. For example, while Smith contemplates injecting saline through both the distal opening of the guide catheter 6 and from the side holes 16a, 16, Smith does not quantify or otherwise distinguish the amount of saline expelled through the distal opening from the amount of saline expelled through the side holes 16a, 16 in calculating the flow parameter. Because this value is not quantified or distinguished in the disclosed calculation, Smith does not calculate its flow parameter as a function of passage of an indicator through a terminal port.

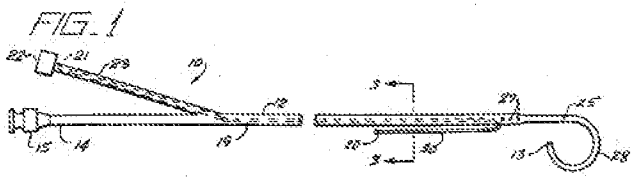
Since Smith does not disclose or suggest, among other things, calculating blood flow rate as a function of passage of an indicator through a terminal port, as recited by independent Claim 14, Applicant respectfully traverses the

rejection of independent Claim 14 over Smith. Reconsideration is respectfully requested.

Claim Rejections under 35 U.S.C. §103

Claim 14 also stands rejected under 35 U.S.C. §103(a) as being unpatentable over Webster. Applicant respectfully traverses this rejection as Webster does not disclose or suggest, among other things, calculating blood flow as a function of passage of an indicator through a terminal port.

As the Office Action expressly indicates, Webster does not explicitly teach that an indicator passes through a terminal port. Instead, Webster teaches that "the passage 16 effectively terminates at the portion of tube 12 where reduced diameter anterior terminal portion 25 commences." (Webster, col. 5, ll. 44-46.)



Based on these teachings, Applicant respectfully disagrees with the assertion that leaked fluid would occur upstream of the temperature sensors disclosed in Webster, and that the fluid would pass the sensors such that measuring would at least be partially based on the passage of the indicator through the terminal port. Such assertions are completely contrary to the teachings of Webster. Because the anterior end is "effectively closed," and the fluid passage 16 effectively terminates at a location upstream of the distal end of the tube 12, fluid is not permitted to escape the distal end of the tube 12

through the passage 16. Instead, the total area of apertures 27 is "substantially larger than the area of the opening of the reduced interdiameter of the tube to the anterior end of the tube after guide wire 26 has been withdrawn from the catheter." (Webster, col. 5, ll. 39-44.) Thus, in addition to the effectively closed anterior end, the apertures 27 are large enough to allow for the release of liquid therethrough without allowing such liquid to pass through the anterior end.

However, assuming arguendo that one could, despite the above teachings to the contrary, construe Webster to teach that leaked fluid would pass through the effectively closed anterior end of the tube 12, Webster still does not disclose or suggest calculating a blood flow rate as a function of passage of an indicator through a terminal port. Similar to Smith, Webster makes no indication whatsoever that any calculations are made as a function of fluid escaping the anterior end. Instead, as discussed in at least column 9 of Webster, a coolant liquid bolus of a predetermined magnitude is simply inserted into, for example, a left ventricle of the patient through the coolant exit apertures 27 to mix with the blood already present in the ventricle. A thermistor is then used to ascertain the temperature of the coolant liquid injected into the ventricle and a thermodilution washout curve is then created using this information. Because the amount of liquid allegedly passing through the anterior end of the tube 12 is not quantified or distinguished in the disclosed calculation, Webster does not calculate a flow parameter as a function of passage of an indicator through a terminal port.

Since Webster does not disclose or suggest, among other things, calculating a blood flow rate as a function of passage of an indicator through a terminal port, applicant respectfully traverses the rejection of independent Claim 14 as obvious over Webster. Reconsideration is respectfully requested.

Claims 16-22 and 28 depend directly or indirectly from independent Claim 14. Therefore, each of these dependent claims is allowable for at least the same reasons discussed above with regard to independent Claim 14. In addition, each of these dependent claims recite unique combinations that are neither taught nor suggested by the applied prior art, and therefore each is also separately patentable.

New Claims

None of the applied prior art either discloses or suggests, among other things, sensing an indicator intermediate a terminal port and an injection port, as recited by new Claims 28 and 29. Instead, as disclosed in Smith, the injected bolus is sensed by the sensor 4 distal to the distal end of the catheter 6 and auxiliary catheter 14. Moreover, the thermistors 40, 42 disclosed in Webster are configured to sense the injected bolus proximal to the apertures 27. For at least these reasons, new Claims 28 and 29 are allowable, and Applicant's requests consideration and allowance of these new claims.

Therefore, each of the pending claims, Claims 14, 16-22, 28, and 29 are in condition for allowance. Should the Examiner consider that additional amendments are necessary to place this application in condition for allowance,

the favor is requested of a telephone call to the undersigned for the purposes of discussing such amendments.

Please grant any extensions of time necessary for the filing of this Amendment. Please also charge any additional required fees due to our deposit account 03-3875.

Respectfully submitted,

Dated: October 14, 2009

Dominic P. Ciminello, Reg. No. 54,038
Harter Secrest & Emery LLP
1600 Bausch & Lomb Place
Rochester, New York 14604
Telephone: 585-232-6500
Fax: 585-232-2152